

REMARKS

Favorable reconsideration of this application is respectfully requested.

Claims 70 and 98 have been amended to set forth the immersion of the tissue sample. Support for this subject matter may be found in the specification, for example, on page 24, line 8 to page 25, line 6. Claims 70 and 98 have also been amended to set forth the distance between the tissue sample and the transducer. Support for this subject matter may be found in the specification, for example, on page 11, line 16 and page 27, lines 4-5. Claims 107 and 110 have been added to set forth multiple heads on a transducer. Support for this subject matter may be found in the specification, for example, on page 14, lines 7-10. Claims 108, 109, 111 and 112 have been added to set forth the movement of a single transducer relative to the sample. Support for this subject matter may be found in the specification, for example, on page 14, lines 20-22.

Applicant submits that these amendments do not constitute new matter, and their entry is requested.

Claims 70, 72-75, 77-79, 92-96 and 98-112 are pending in this application.

Claims 70, 72-75, 77, 78, 92-96 and 105 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Northrup et al. (US 5,639,423) in view of Gravlee, Jr. (US 3,961,097), Ishibashi et al. (US 5,984,881) and Antich et al. (US 5,197,475). Applicant respectfully traverses.

With the exception of Antich et al., the Examiner cited each of these references in the Office Action dated 16 April 2008. The Examiner's grounds for the rejections in the Office action dated 02 January 2009 are identical to the previous Office Action. The Applicant argued in his response to the 16 April 2008 Office Action, that each of the structural limitations of claim 70 were not disclosed in any of the prior art cited by the Examiner. For example, none of the ultrasound transducers disclosed in the previously cited references are immersed in the solutions of the Applicant's invention. In response to these arguments, it appears that the

Examiner is attempting to cite Antich et al. to remedy this deficiency. According to the Examiner:

Antich et al. disclose that transducers may be external to the container such as a bag and transmit ultrasound through the container, as done by Gravlee, Jr., or the transducer can be immersed in the container (column 8, lines 20-30), thus demonstrating that these two locations of the transducer are equivalent structures known in the art.

(emphasis added). See top of page 5, Office Action. However, the cited passage contains no disclosure of an immersed transducer. More than likely, the Examiner meant to cite col. 7, lines 20-30 instead, which is the only passage in Antich which supports the Examiner's argument. This passage (with emphasis added) discloses that:

[t]he ultrasound transducers are in acoustic contact with the water bag. For example, the transducers can be immersed in the bag, or can be external to the bag but contacting it such that the ultrasound is conducted through the bag to or from the transducers. The applicator head **62** is positioned so that its focal point on the bone surface and its axis is aligned with the axis of the normal to the bone surface **14** at the point of interest as illustrated in FIG. **4**.

On first glance, this passage appears to disclose a claimed limitation of the instant invention, but the preceding passage makes clear that the Applicant's invention is distinguishable from Antich et al. On col. 7, lines 14-20, Antich discloses that the focal point on the bone surface is not immersed in solution during in situ or in vivo analysis of a patient's bone. Antich et al., referring to FIG. **4**, teaches that:

[. . .] a pressurized, temperature controlled water bag or water bolus **64** is interposed between the applicator head **62** and patient, assuring good contact and match with the surface of the body of the patient. The water bag **64** has at least one surface that is flexible and can be positioned on the surface of a human body in proximity to a bone.

Thus, although Antich's transducer is immersed in a container, the focal point of the transducer is not immersed in the same solution that the transducer is immersed in.

On the other hand, the Applicant's invention requires that the focal point of the transducer and the transducer are immersed in the same solution. Without acquiescing to the propriety of the Examiner's rejection, claim 70 has been amended to more clearly specify that the tissue sample, i.e., the focal point of the transducer, is immersed in the same solution that the transducer is immersed in. Claim 70 also requires a distance within 2 inches between the transducer and the tissue sample, both of which are immersed in the same solution.

Although Antich et al. discloses the immersion of the focal point of the transducer, it cannot anticipate the Applicant's invention. Antich et al. discloses only that the focal point of transducer generated ultrasound, i.e., the bone surface, can be immersed in solution (see FIGS. **2-3** and col. 6, lines 61-63) in an ex vivo embodiment. However, Antich et al. never teaches simultaneous immersion of both the transducer and the focal point of transducer generated ultrasound energy. To do so would require the combination of Antich's ex vivo and in vivo embodiments. Given the disclosure of Antich et al., one of ordinary skill in the art would not be led to analyze and diagnose the tendency of a patient's bone to fracture, heal, etc. when that patient's in vivo bone surface is simultaneously immersed in the same solution that the transducer is immersed in. See col. 6, line 61 to col. 7, line 1. Such an embodiment would require surgical removal of live tissue surrounding the patient's bone surface and would not be a "quick and efficient evaluation of treatment of osteoporosis." See Abstract, Antich et al., last sentence. Additionally, the skilled artisan would only take away from Antich et al. that the transducer can be immersed only in one disclosed solution, water. See col. 6, lines 56-61. Consequently, the Examiner cannot combine Gravlee, Jr. with Antich, et al. because simultaneous immersion of both the transducer and a tissue sample in the same solution was not known in the art.

Accordingly, claim 70 is allowable over Northrup et al., in view of Gravlee, Jr., Ishibashi et al. and Antich et al. Furthermore, claims 72-75, 77, 78, 92-96 and 105, 107-109, each depending from claim 70, are also allowable, at least for the reasons discussed above.

In view of the above remarks, Applicant submits that Northrup et al., in view of Gravlee, Jr., Ishibashi et al. and Antich et al. does not anticipate the claimed subject matter. Withdrawal of these rejections is requested.

Claims 79, 98-104, and 106 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Northrup et al. (US 5,639,423) in view of Gravlee, Jr. (US 3,961,097), Ishibashi et al. (US 5,984,881), and Antich et al. (US 5,197,475), as applied to claim 70, and further in view of Vago (US 5,665,141). With the exception of Antich et al., as noted above, the Examiner cited each of these references in the Office Action dated 16 April 2008. However, even with the additional citation of Antich et al. to the previously cited references, there is no disclosure for each of the structural limitations of independent claims 70 and 98. Particularly, as noted above, there is no disclosure for the simultaneous immersion of both the transducer and a tissue sample in the same solution. Nor is there any disclosure with regard to a distance within 2 inches between the transducer and the tissue sample, both of which are immersed in the same solution. Consequently, the Examiner cannot combine Gravlee, Jr. with Antich, et al. because simultaneous immersion of both the transducer and a tissue sample, within 2 inches, in the same solution was not known in the art.

Notwithstanding the failure of the cited references to disclose all of the structural features recited by Claims 70 and 98, the Office Action still fails to establish why one of ordinary skill in the art would combine the teachings of these disparate references. Northrup discloses that the purpose of his sonication is to disrupt and expose cell components through lysis, which are then used by subsequent PCR processes. See, e.g., col. 5: lines 44–47, 52–57, 57–61. The Examiner's citation of col. 5, lines 58-60 for the proposition that Northrup et al. teaches a system that "may be used to process tissues" is in error because the Examiner reads the sentence out of context. Rather, in the full paragraph starting at col. 5, line 44, Northrup teaches that pre-PCR use of ultrasound leads to the destruction of his samples rather than their preservation.¹ Similarly, Ishibashi's "therapeutic ultrasonic waves are generated continuously . .

¹ The instant application seeks to preserve the morphology of samples, for subsequent processes, through the process of fixing in order to provide information about proteins and nucleic acids, as well

. thereby heating and necrotizing an abnormal tissue such as cancer" (col. 10, lines 30-34), which, of course, results in the destruction of the abnormal tissue. To the contrary, Gravlee discloses that the intensity of his ultrasonic energy "must be maintained at a level below the level at which damage to cells in the tissue occurs" (col. 3, lines 50-52). Likewise, Vago discloses that "the frequency and intensity of the ultrasound is selected to avoid tissue damaging effects to a bather." See col. 7, lines 61-62. Finally, Antich discloses the noninvasive use of ultrasound for the "quick and efficient evaluation of treatment of osteoporosis" without destruction of live tissue. See col. 6, line 61 to col. 7, line 1 and col. 1, lines 34-38. Accordingly, Applicant submits that one of ordinary skill in the art would not combine these references due to their inapposite purposes, i.e., the destruction of tissue (Northrup and Ishibashi) as compared to its preservation (Gravlee and Vago and Antich). Consequently, the Office Action has failed to establish a *prima facie* case of obviousness, and Applicant suspects that the Office Action is engaging in impermissible hindsight reconstruction in order to arrive at the claimed invention.

Accordingly, claims 70 and 98 are allowable over Northrup et al., in view of Gravlee, Jr., Ishibashi et al. and Antich et al. and Vago. Furthermore, claim 79, depending from claim 70, and claims 99-104, and 106, 110-112 each depending from claim 98, are also allowable, at least for the reasons discussed above.

In view of the above remarks, Applicant submits that Northrup et al., in view of Gravlee, Jr., Ishibashi et al. and Antich et al. and Vago does not anticipate the claimed subject matter. Withdrawal of these rejections is requested.

The Examiner has rejected claims 70, 72-74, 93-95, 98, 100-103 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of Chu (US 7,262,022). Filed concurrently herewith, Applicant is filing a terminal disclaimer to overcome the rejection. Thus, Applicant respectfully requests reconsideration and withdrawal of the rejection.

as the histological appearance of the tissue sample. See, e.g., page 1, lines 23-26 of Specification. Indeed, Northrup's "subsequent techniques," discussed, for example, at Col. 6:1-10, do not involve any quality of the sample other than the extracted DNA.

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Att'y Dkt: 2313-116

The Examiner has provisionally rejected claims 70, 79, 98-99, 103, 105-106 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 92-108 Of Chu (US Appn. 2007/0072258), filed 25 September 2006. Because the cited reference has yet to issue, Applicant requests that the Examiner hold this rejection in abeyance pending allowance of claims in either the present application or US Appn. 2007/0072258. See M.P.E.P. 804.I.B.1.

In view of the amendments and remarks presented herein, Applicant respectfully submits that this application is in condition for allowance and should now be passed to issue. Reconsideration and early Notice of Allowance is requested. The Director is authorized to charge any fees or overpayment to Deposit Account No. 02-2135.

Respectfully submitted,
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